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09/734,787	12/13/2000	Mark A. Ritchart	END-712	6087

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EXAMINER
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FOREMAN, JONATHAN M

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3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**Group 3700**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/734,787  
Filing Date: December 13, 2000  
Appellant(s): RITCHART ET AL.

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Gerry Gressel  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 4/19/05 appealing from the Office action mailed 8/16/04.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Merriam-Webster's Collegiate Dictionary, 2001, 10<sup>th</sup> ed., 626, 695, 719.

U.S. Patent No. 2,198,319 to Silverman

U.S. Patent No. 4,393,872 to Reznik et al.

U.S. Patent No. 5,476,101 to Schramm et al.

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**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 – 19 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 2,198,319 to Silverman.

In reference to claims 17 – 19 and 35, Silverman discloses a method including piercing tissue with an instrument comprising an outer hollow cannula (10) and an inner member (14) having a distal end portion disposed within the hollow cannula; positioning the hollow cannula within the tissue at a desired tissue site (Col. 2, lines 4 – 6); actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally (Col. 2, lines 6 – 9), relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted (Col. 2, lines 9 – 14); actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion (Col. 2, lines 14 – 19); and withdrawing the instrument and tissue sample from the tissue (Col. 2, lines 21 – 23). Silverman discloses grasping a tissue sample with a pair of jaws (Figure 5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

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subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No.

2,198,319 to Silverman as applied to claim 17 above, and further in view of U.S. Patent No.

4,393,872 to Reznik et al.

In reference to claim 20, Silverman discloses grasping a tissue sample, but fails to disclose using a plurality of hooked extractors. Reznik et al. teaches the use of a plurality of hooked extractors (16) to grasp a tissue sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the grasping members as disclosed by Silverman with the hooked extractors as taught by Reznik et al. to enable the physician to more readily grasp or grip the target tissue (Col. 3, lines 2 – 4).

Claim 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,198,319 to Silverman as applied to claim 17 above, and further in view of U.S. Patent No. 5,476,101 to Schramm et al.

In reference to claims 21 and 22, Silverman discloses manually actuating the first and second mechanisms. Schramm et al. teaches a biopsy apparatus having a first (55) and second (56) spring element to store energy to drive an inner and outer cannula (Col. 6, lines 9 – 16). It would have been obvious to one having ordinary skill in the art to modify the device as disclosed by Silverman to include a first and second spring element to store energy to drive the outer hollow cannula and the inner member to allow for a more precise automated sampling procedure. Furthermore, the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. *In re Venner*, 262, F.2d 91, 120 USPQ 192 (CCPA1955).

**(10) Response to Argument**

Applicant's arguments have been fully considered but they are not persuasive.

In regard to the rejection of claims 17 – 19 and 35 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 2,198,319 to Silverman, Applicant asserts that Silverman fails to disclose actuation of a first mechanism to move the distal end portion of an inner member distally and actuation of a second mechanism to move the outer hollow cannula distally. Applicant asserts that at most, Silverman may be viewed as disclosing manual hand operation of the device by manipulation of the operating hub (15) or needle hub (10). Applicant asserts that such operation can not be properly construed as actuation of a first mechanism, nor actuation of a second mechanism. However the Examiner disagrees. Silverman discloses actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally (Col. 2, lines 6 – 9), relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted (Col. 2, lines 9 – 14); actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion (Col. 2, lines 14 – 19). Operating hub (15) and needle hub (12) are considered by the Examiner to be the first and second mechanisms respectively, in that when the operator actuates each respective hub, mechanical energy is then exerted to the outer cannula and inner member. A mechanism need only be “a piece of machinery” (Webster’s 10<sup>th</sup> ed.). A machine is “a constructed thing whether material or immaterial” (Webster’s 10<sup>th</sup> ed.). In the present case, each hub is a piece of machinery.

In regard to claim 19, Applicant asserts that Silverman fails to disclose grasping a tissue sample with a pair of jaws associated with the distal portion of the inner member. The Examiner disagrees. Silverman clearly discloses grasping a tissue sample with the distal portion of the inner member (Col. 2, lines 16 – 19). Jaws are merely “either of two or more opposable parts that open

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and close for holding or crushing something between them” (Webster’s 10<sup>th</sup> ed.). In this regard, the split end portion of the inner member as disclosed by Silverman is properly construed as a pair of jaws.

In regard to the rejection of claim 20 under 5 U.S.C. 103(a) as being unpatentable over Silverman in view of Reznik et al., Applicant asserts that the Examiner has failed to meet the burden of providing a prima facie case of obviousness. Applicant asserts that Reznik et al. teaches away from the proposed combination of modifying the radially expanding member as disclosed by Silverman to include hooked extractors as taught by Reznik et al. Applicant asserts that because Silverman teaches the divergently pointed and beveled ends of the needle being needed to spread apart during insertion of the needle, that one would not have been motivated to replace the ends as disclosed by Silverman with the inwardly turned prongs as taught by Reznik et al. Applicant is suggesting that by replacing the divergently pointed ends of Silverman with the inwardly turned prongs disclosed by Reznik et al., the advantage of the divergently pointed needle portions (i.e. allowing the needle to separate) is defeated. However, the Examiner disagrees. Reznik et al. forms the hooked extractors (16) with a pre-formed bend that automatically diverges upon being extended beyond the end of the cannula (Col. 3, lines 17 – 19; Figure 5). Because the hooked extractors as taught by Reznik et al. diverge and provide the advantage of enabling the physician to more readily grasp or grip the target tissue (Col. 3, lines 2 – 4), the Examiner maintains that it would have been obvious to one having ordinary skill in the art to replace the grasping members as disclosed by Silverman with the hooked extractors as taught by Reznik et al.

In regard to the rejection of claims 21 and 22 under 5 U.S.C. 103(a) as being unpatentable over Silverman in view of Schramm et al., Applicant asserts that the rejection is improper in that the Examiner has not met the burden of providing a prima facie case of obviousness and has improperly

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relied on the Applicant's teachings in hindsight. However, the Examiner maintains that a prima facie case of obviousness has been met and that hindsight was not the motivation of the combination of references. The teaching gained by the disclosure of Schramm et al. is the benefit of using stored energy in a spring element to aid in performing an automated biopsy sampling procedure (Col. 5, lines 53 – 56), not the positioning of the needles (i.e. the positioning of the inner needle being exposed). By adding a spring element and associated release mechanisms to the device as disclosed by Silverman, one would reasonably expect to perform a more precise, automated biopsy that would meet the limitations of the claimed method. Additionally, the court held that broadly providing an automatic or mechanical means to replace a manual activity that accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262, F.2d 91, 120 USPQ 192 (CCPA1955). Even without the disclosure of Schramm et al., one having ordinary skill in the art would see the benefits of modifying the device as disclosed by Silverman to become an automatic device.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.



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For the above reasons, it is believed that the rejections should be sustained.

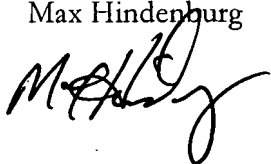
Respectfully submitted,

Jonathan Foreman

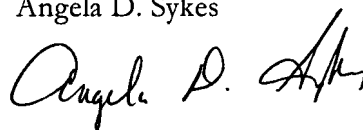


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